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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,361	09/12/2003	David A. Mackiewicz	ENDOS 64949 (4164P)	6762

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FULWIDER PATTON LLP
HOWARD HUGHES CENTER
6060 CENTER DRIVE, TENTH FLOOR
LOS ANGELES, CA 90045

EXAMINER

HOUSTON, ELIZABETH

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/661,361

Applicant(s)

MACKIEWICZ ET AL.

Examiner

Elizabeth Houston

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 23-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22, 32 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 031804, 010906, 112006.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Species I, claims 1-22, 32 and 33, in the reply filed on 08/28/06 are acknowledged.
2. Claims 23-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 08/28/06.

Claim Objections

3. Claim 6 is objected to because of the following informalities: Claim 6 recites the limitation "the V-shaped opening" in line 1 and the limitation "the C-shaped region" in line 2. There is insufficient antecedent basis for these limitations in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 1, 3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Goicoechea et al. (USPN 5,609,627)**

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6. Goicoechea discloses a stent comprising a structural body having a certain level of radiopacity (nitinol) and at least one marker holder integrally formed therein (Fig 4A, the marker holder is the two struts shown holding the marker (17)). The device comprises a radiopaque marker (17) attachable within the marker holder. The marker holder includes a pair of projecting fingers (each strut), which define an opening (space between the two struts) and the radiopaque marker includes a region (part of the marker that lies in the space defined by the two struts), which fits within the opening defined by the fingers. The projecting fingers are connected at a notched region (peak of the undulation where the two struts meet), which allows the projecting fingers to move laterally to accept the radiopaque maker. The opening defined by the projecting fingers of the marker holder is substantially V-shaped and the region formed on the radiopaque marker fits within the opening.

7. Claims 2, 4, 6, 7, 32 and 33 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Goicoechea et al.

8. Goicoechea discloses the stent substantially as claimed as stated above. As to claims 2 and 4, Goicoechea teaches a radiopaque marker attached to the marker holder, but is silent as to how the marker is attached. The claimed phrase "by a heat weld" is being treated as a Product by Process limitation. As to claims 6 and 7, the limitations that "the radiopaque marker defines an angle which is larger than the angle of the V-shaped opening" and "the radiopaque marker has a region adapted to fit within

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the opening defined by the projecting finger that is larger than the opening defined by the projecting finger" are structural limitations that are directed toward the manufacturing process of the stent and are not directed toward the structure of the final product. As such these claims are also being treated as claiming Product by Process limitations. As set forth in the MPEP 2113, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (See MPEP § 2113). Examiner will thus evaluate the product claims without giving much weight to the method of its manufacture.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 8-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goicoechea in view of Duerig et al (USPN 6,503,271).

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11. Goicoechea discloses the device substantially as claimed as stated above except for the limitation that the radiopaque marker is made from a nickel-titanium alloy including a ternary element.

12. Duerig discloses a stent with radiopaque markers that are made from a nickel-titanium alloy with a ternary element that is platinum (Col 10, lines 15-23). Duerig further discloses that use of a micro-alloy is advantageous to overcome the challenge of galvanic corrosion (Col 4, lines 22-24).

13. Goicoechea discloses the stent substantially as claimed as stated above. As to claims 13, 14, 17, 19 and 22, Goicoechea teaches a radiopaque marker attached to the marker holder, but is silent as to how the marker is attached. The claimed phrase "by a heat weld" and "by melting" is being treated as a Product by Process limitation. As to claim 21, the limitations that "the radiopaque marker defines an angle which is larger than the angle of the V-shaped opening" is a structural limitation that is directed toward the manufacturing process of the stent and is not directed toward the structure of the final product. As such this claim is also being treated as claiming a Product by Process limitation. As set forth in the MPEP 2113, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (See MPEP § 2113). Examiner will thus

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evaluate the product claims without giving much weight to the method of its manufacture.

14. Regarding claim 10, Goicoechea discloses the claimed invention except for the atomic percent of platinum. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide platinum in the percentage of between and including 2.5% and 15%, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch* 617 F.2d 272,205 USPQ 215 (CCPA 1980).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

eh




ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

3/2/07